THE ROLE OF USABILITY TESTING AND DOCUMENTATION IN MEDICAL DEVICE SAFETY

Susan G. Feinberg, Ph.D.[1] Barry N. Feinberg, Ph.D.[2]
[1]Director, Usability Testing and Evaluation Center, Illinois Institute of Technology, Chicago, Illinois
[2]Principal Consulting Engineer, Center for Engineering Analysis, Chicago, Illinois

Abstract-Usability testing is a technique that can be used to identify problems users have with a device. If usability testing is employed early in the development cycle, it can identify potential use-related problems and hazards so that they can be addressed early in the design and/or development process. The FDA's Center for Devices and Radiological Health has published a document that provides guidance on medical device use-safety and describes the benefits of usability testing to identify potential hazards[1]. This paper describes the application of usability testing to the design, development, and use of a functional neuromuscular (cough) stimulator and the accompanying documentation. The purpose of the user testing was to observe participants using a device in a realistic situation. Iterative design and user testing is an effective way to 1. reduce or eliminate use-related hazards, 2. make an interface intuitive, 3. alert users to errors, and 4. provide aids for safe operation.
Keywords-Usability testing, user-safety, human factors, user interface

I. PRODUCT DEVELOPMENT THROUGH USER-TESTING

The FDA looks at medical devices as a potential source of harm to users. When devices are potentially harmful, they become hazards that can be broken down into two major classes: hazards due to device failure or malfunction and hazards due to device use. In this paper we focus on the hazard due to device use and the role of usability testing in the reduction of user hazards resulting from the interaction between the user and the medical device.

To illustrate how usability testing is an important aspect of hazard reduction in the development of a medical device, our team designed, developed and user tested a cough stimulator for quadriplegics to induce a physiologic cough.

It is important for people to cough, not only to clean their lungs and throat but to supplement ciliary action in removing secretions from the airways. A normal cough supplements this ciliary action, but failure to cough and remove secretions predisposes the individual to health complications such as pneumonia. A spinal cord-injured patient is unable to cough, a situation that prevents bronchial cleansing and thus predisposes the patient to respiratory infection.

Usually, the spinal cord-injured individual would require the help of a therapist to assist with coughing. However, a cough-assist device would allow the spinal cord-injured individual to self-assist in this important function.

II. PURPOSE OF THE PROJECT

An inter-professional project involved a team of biomedical engineers, usability experts, and students in biology, engineering and design at the Illinois Institute of Technology and the Pritzker Institute of Medical Engineering. The product development plan had four objectives:

- To iteratively user-test and redesign the device and the documentation so as to utilize the device effectively and reduce the possibility of hazards to the user,
- To continue the development of devices to assist quadraplegics to cough, specifically by modifying the existing cough device to allow the patient to control the cough device as a result of the usability testing,
- To produce and user-test a user-manual giving information and instructions on how to operate the cough-device,
- To produce and user-test a video describing the device and instructing an individual in how to use the device.

The technical/design side of the project required the selection of a switch that the spinal cord-injured patient could use independently. The manual and the video tape would aid the individual in the use of the cough device. Iterative testing and redesign allowed the team to observe the performance of users in realistic situations.

III. METHODOLOGY

The products were researched, developed and tested on site at the Pritzker Institute of Medical Engineering at Illinois Institute of Technology and at the Rehabilitation Institute of Chicago .

1) *The technical device*: The technical ergonomic problems associated with the self-assist cough device revolved around assembling a trigger that the spinal cord-injured individual could use to initiate the stimulation. We first approached this project by outlining the specifications for the desired switch. The switch needed to have a large surface activation area requiring little pressure to activate it and some sort of mounting capabilities. The switch also had to be versatile and adaptable for patients with a wide range of mobility.

Figure 1 illustrates a component of the cough stimulator, and Figure 2 illustrates the interconnectivity of components.

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Abstract

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Figure 1. Cough stimulator electrode component

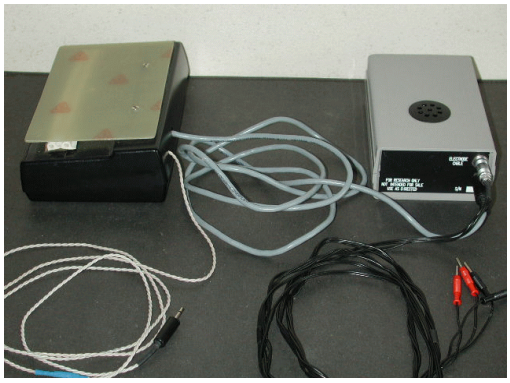
Figure 2. Interconnection of cough stimulator components

2) *The user manual*: We examined other instructional manuals designed for quadraplegics and outlined the parts of our manual: table of contents, descriptions, instructions, illustrations, consent forms, glossary, and list of references. The working device was demonstrated so that the group could write accurate and clear instructions for the patient, patient labeling being an important part of aids to the user[2].

3) *The video tape*: We previewed other instructional video tapes prepared for quadraplegics. For our video tape we developed a scenario, used members of our group to video tape the placement and use of the trigger device, taped "talking heads," and processed stills from the video tape for illustrations that we included in the manual, and edited the tape.

4) *Usability tests*: With respect to the formal usability test, we user tested only the device: both a caregiver and patients performed one task: activating the device. Based on our observation and debriefing of the users, we had successfully produced a cough device that the spinal cord-injured individual could self-activate. But we learned as a result of our usability test that we could improve upon the design of the cough stimulator.

5) *Findings:* Based on our usability studies we have plans to redesign the cough stimulator in the following ways, redesign being part of the iterative process [3]:

- Add a buzzer as a signal to the patient to take a breath so that the patient will be in synch with the device. If the patient does not prepare to take a breath, the stimulator will be less effective in assisting the patient to cough. In worst cases, the device may not be effective at all, posing a hazard to the patient who falsely believes that the device is assisting in the reduction of a medical problem such as pneumonia.

- Add a time delay so that the patient can prepare from the moment of activating the switch to actually receiving the stimulus and not have the stimulator interfere with other devices such as a ventilator.

Furthermore, at Illinois Institute of Technology we have a state of the art Usability Testing and Evaluation Center to run formal usability tests on medical devices. In our opinion, the user testing of medical devices is critical to the safety and effectiveness of their use. In their guidelines, the Center for Devices and Radiological Health states that usability testing can

- reduce or eliminate use-related hazards
- make an interface intuitive
- alert users to errors
- provide aids for safe operation.

Our experience with the usability testing of the cough stimulator and other medical devices confirms their statements.

IV. CONCLUSIONS

The Center for Devices and Radiological Health explains in their document that usability testing is "a systematic collection of data from users (participants) using a device (or device component) in realistic situations." In our Usability Testing and Evaluation Center we follow a methodology that rigorously user tests devices, components of devices, and other user interfaces with which humans interact. Research indicates that 5-6 users can identify 80% of the global problems by user testing a product.

Our usability testing incorporates the following procedure:

1. Analysis of issues with the device or interface (includes interview with client and heuristic evaluation of the device or interface),

2. Selection of participants who represent the intended users,

3. Preparation of test materials (includes participant profile, consent forms, scenarios, real tasks, and debriefing questionnaire),

4. Observation of user performance using the UTEC lab or equipment with test personnel (includes a test administrator and technical staff to run 6 usability tests and debriefing interviews, each test lasting approximately 1 hour),

5. Presentation of results (includes executive summary, data tables with narrative descriptions, identification of potential use-related hazards and the development of specific recommendations to

address them.

In conclusion, we have shown how usability testing in the product development cycle of a medical device can help to minimize hazards to a user. We applaud the FDA's guidance in describing the importance of usability testing in their papers on medical device use-safety.

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REFERENCES

1. FDA, Center for Devices and Radiological Health, "Medical Device Use-Safety: Incorporating Human Factors Engineering in Risk Management," July 18, 2000.

2 FDA, Center for Devices and Radiological Health, "Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, " April 19, 2001.

3 D. Sawyer, "Do It by Design: An Introduction to Human Factors in Medical Devices," FDA Center for Devices and Radiological Health.